

Message

From: Arthur Toscano [arthur.toscano@bayer.com]
Sent: 2/10/2023 9:19:50 PM
To: Schmid, Emily [Schmid.Emily@epa.gov]; Hathaway, Margaret (she/her/hers) [Hathaway.Margaret@epa.gov]; Roe, Lindsay [Roe.Lindsay@epa.gov]; Crawford, Lydia (she/her/hers) [Crawford.Lydia@epa.gov]
CC: George Sabbagh [george.sabbagh@bayer.com]; BCSReg_Archive [esepamailbox@bayer.com]
Subject: RE: XtendiMax Label Amendment
Attachments: XtendiMax updated FIFRA label amendment cover letter 2023-02-10 rev01.pdf; 8570-1_Application_XtendiMax_264-1210_2023-02-10.pdf; 264-1210_XtendiMax® With VaporGrip® Technology_02_10_2023.pdf; 264-1210_XtendiMax® With VaporGrip® Technology_02_10_2023_BASE.PDF

Flag: Follow up

Hi Emily,

We would like to let you know that Bayer has submitted an updated version of the XtendiMax master label through CDX this afternoon, to support Bayer's fast-track label amendment proposal.

For your convenience, please see attached courtesy copies of the submission documents.

Please let us know if you have any questions or comments.

Have a great weekend.

Arthur Toscano
Senior Regulatory Affairs Manager
Broad Acre & Trait Use
Crop Protection Regulatory Affairs

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Bayer U.S. – Crop Science
R&D Regulatory Science
700 Chesterfield Pkwy W
Chesterfield, MO 63017, USA
Phone: +1 (314) 302-2583
E-mail: arthur.toscano@bayer.com
Web: <http://www.bayer.com>

From: Arthur Toscano
Sent: Tuesday, February 7, 2023 2:32 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>; Hathaway, Margaret <Hathaway.Margaret@epa.gov>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Cc: George Sabbagh <george.sabbagh@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: XtendiMax Label Amendment

Hi Emily,
I hope this message finds you well.

We would like to share that Bayer has submitted an updated version of the XtendiMax master label today through the portal.

For your convenience, please see attached the submission documents

- Form 8570-1
- Cover letter

- Updated master label (both the highlighted and the clean copies)
- CDX package transmittal message

Below are the application(s) included in this package and their tracking number(s):

Sec3-Amend-000001: CDX_2023_017592

Company Name: BAYER CROPSCIENCE LP

Company Number: 264

Please let us know if you have any questions or comments.

Thanks,

Arthur Toscano

Senior Regulatory Affairs Manager

Broad Acre & Trait Use

Crop Protection Regulatory Affairs

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R&D Regulatory Science

700 Chesterfield Pkwy W

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Phone: +1 (314) 302-2583

E-mail: arthur.toscano@bayer.com

Web: <http://www.bayer.com>

From: Arthur Toscano

Sent: Tuesday, January 31, 2023 8:47 AM

To: Schmid, Emily <Schmid.Emily@epa.gov>; Hathaway, Margaret <Hathaway.Margaret@epa.gov>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>

Cc: George Sabbagh <george.sabbagh@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>

Subject: RE: XtendiMax Label Amendment

Hi Emily,

Good morning.

Bayer would like to withdraw the submission made on Friday, Jan 27, 2023 through CDX (courtesy copies sent yesterday, attached), so Bayer current fast-track label amendment proposal stays as indicated in the Jan 6, 2023 submission.

Please let us know if you have any questions or comments.

Thanks,

Arthur Toscano

Senior Regulatory Affairs Manager

Broad Acre & Trait Use

Crop Protection Regulatory Affairs

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E-mail: arthur.toscano@bayer.com
Web: <http://www.bayer.com>

From: Arthur Toscano

Sent: Monday, January 30, 2023 11:25 AM

To: Schmid, Emily <Schmid.Emily@epa.gov>; Hathaway, Margaret <Hathaway.Margaret@epa.gov>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>

Cc: George Sabbagh <george.sabbagh@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>

Subject: RE: XtendiMax Label Amendment

Hi Emily,

Good afternoon.

I hope you had a great weekend.

We wanted to share that Bayer has submitted, through CDX on Friday (Jan 27), an updated version of the XtendiMax fast-track label amendment request documents.

For your convenience, please see attached courtesy copies of the submitted documents:

- Cover letter
- Revised master label (both the highlighted and the clean version)
- 8570-1 form
- CDX package transmittal confirmation message

Below are the application(s) included in this package and their tracking number(s):

Sec3-Amend-000001: CDX_2023_017127

Company Name: BAYER CROPSCIENCE LP

Company Number: 264

Please let us if you have any questions or comments.

Thanks,

Arthur Toscano

Senior Regulatory Affairs Manager

Broad Acre & Trait Use

Crop Protection Regulatory Affairs

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Bayer U.S. – Crop Science

R&D Regulatory Science

700 Chesterfield Pkwy W

Chesterfield, MO 63017, USA

Phone: +1 (314) 302-2583

E-mail: arthur.toscano@bayer.com

Web: <http://www.bayer.com>

From: Arthur Toscano

Sent: Friday, January 6, 2023 4:38 PM

To: Schmid, Emily <Schmid.Emily@epa.gov>; Hathaway, Margaret <Hathaway.Margaret@epa.gov>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>

Cc: George Sabbagh <george.sabbagh@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>

Subject: RE: XtendiMax Label Amendment

Hi Emily,

Happy New Year!

We would like to let you know that Bayer has submitted through CDX early this afternoon a revised version of the XtendiMax master label for the fast-track label amendment process.

For your convenience, please see attached the revised master label (both the highlighted and the clean versions), the cover letter, the 8570-1 form and the transmittal message.

Below are the application(s) included in this package and their tracking number(s):

Sec3-Amend-000001_264-1210_Updated Fast Track AM_Updated Master LB: CDX_2023_015929

Company Name: BAYER CROPSCIENCE LP

Company Number: 264

Please let us know if you have additional questions or comments.

Thanks,

Have a great weekend.

Arthur Toscano

Senior Regulatory Affairs Manager

Broad Acre & Trait Use

Crop Protection Regulatory Affairs

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Bayer U.S. – Crop Science

R&D Regulatory Science

700 Chesterfield Pkwy W

Chesterfield, MO 63017, USA

Phone: +1 (314) 302-2583

E-mail: arthur.toscano@bayer.com

Web: <http://www.bayer.com>

From: Schmid, Emily <Schmid.Emily@epa.gov>

Sent: Wednesday, December 14, 2022 8:42 AM

To: Arthur Toscano <arthur.toscano@bayer.com>; Hathaway, Margaret <Hathaway.Margaret@epa.gov>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>

Cc: George Sabbagh <george.sabbagh@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>

Subject: RE: XtendiMax Label Amendment

Thank you, Arthur!

From: Arthur Toscano <arthur.toscano@bayer.com>

Sent: Tuesday, December 13, 2022 6:01 PM

To: Schmid, Emily <Schmid.Emily@epa.gov>; Hathaway, Margaret <Hathaway.Margaret@epa.gov>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>

Cc: George Sabbagh <george.sabbagh@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>

Subject: RE: XtendiMax Label Amendment

Hi Emily,

We have concluded the submission through CDX.

For your convenience, please see attached courtesy copies of the documents that were submitted (cover letter and amended master label, both the highlighted and the clean version), and the transmittal message.

Below you will find the tracking number:

Sec3-Amend-00001_264-1210_Updated Fast Track Amendment_updated Master Label: CDX_2022_015170

Company Name: BAYER CROPSCIENCE LP

Company Number: 264

Please let us know if you have additional questions or comments.

Thanks,

Arthur Toscano

Senior Regulatory Affairs Manager

Broad Acre & Trait Use

Crop Protection Regulatory Affairs

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Bayer U.S. – Crop Science

R&D Regulatory Science

700 Chesterfield Pkwy W

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From: Arthur Toscano

Sent: Monday, December 12, 2022 11:58 AM

To: Schmid, Emily <Schmid.Emily@epa.gov>; Hathaway, Margaret <Hathaway.Margaret@epa.gov>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>

Cc: George Sabbagh <george.sabbagh@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>

Subject: RE: XtendiMax Label Amendment

Hi Emily,

Thanks for your response.

We are working on the submission through the portal. I believe it will be concluded by tomorrow morning or earlier. I will let you know as soon as we have submitted it, and will be sending you the submission documents along with their respective tracking number.

Thanks,

Arthur Toscano

Senior Regulatory Affairs Manager

Broad Acre & Trait Use

Crop Protection Regulatory Affairs

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Web: <http://www.bayer.com>

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From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Monday, December 12, 2022 9:31 AM
To: Arthur Toscano <arthur.toscano@bayer.com>; Hathaway, Margaret <Hathaway.Margaret@epa.gov>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Cc: George Sabbagh <george.sabbagh@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: XtendiMax Label Amendment

Hi Arthur,

Thank you for sending this. If you haven't already, could you submit it through the portal?

Thank you,
Emily

From: Arthur Toscano <arthur.toscano@bayer.com>
Sent: Friday, December 9, 2022 7:43 PM
To: Hathaway, Margaret <Hathaway.Margaret@epa.gov>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Cc: George Sabbagh <george.sabbagh@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: XtendiMax Label Amendment

Hi Lindsay, Meg, Emily and Lydia,

Please see attached the revised version of the XtendiMax label related to the label amendment request submitted on 10/18/2022, updated after discussions with the agency.

Please let us know if you have any questions or comments.

Thanks,

Arthur Toscano
Senior Regulatory Affairs Manager
Broad Acre & Trait Use
Crop Protection Regulatory Affairs

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Web: <http://www.bayer.com>

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From: Hathaway, Margaret <Hathaway.Margaret@epa.gov>

Sent: Wednesday, October 19, 2022 4:44 PM

To: Arthur Toscano <arthur.toscano@bayer.com>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>

Cc: George Sabbagh <george.sabbagh@bayer.com>

Subject: RE: XtendiMax Label Amendment

Thank you, Arthur. Courtesy copy received. My office appreciates this update from Bayer.

Best regards,
Meg

Margaret Hathaway (Meg) (*she/her/hers*)
Senior Regulatory Specialist
U.S. Environmental Protection Agency
OCSPP: Office of Pesticide Programs
Registration Division – Herbicide Branch
hathaway.margaret@epa.gov
(202) 566-2730

From: Arthur Toscano <arthur.toscano@bayer.com>

Sent: Tuesday, October 18, 2022 7:02 PM

To: Roe, Lindsay <Roe.Lindsay@epa.gov>; Hathaway, Margaret <Hathaway.Margaret@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>

Cc: George Sabbagh <george.sabbagh@bayer.com>

Subject: XtendiMax Label Amendment

Hi Lindsay, Meg, Emily and Lydia,
I hope you are all doing well.

We wanted to share that Bayer has submitted the updated label amendment request for XtendiMax.
For your convenience, please find attached copies of the submission documents, including the transmittal message.

Please let us know if you have any comments or questions.

Thanks,

Arthur Toscano
Senior Regulatory Affairs Manager
Broad Acre & Trait Use
Crop Protection Regulatory Affairs

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